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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/294,663 04/19/99 GRANADOS

EXAMINER

R BTI-39-C1P

020808 HM22/1212  
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ART UNIT PAPER NUMBER

IBRAHIM, M

12

DATE MAILED:

1638

12/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/294,663

Applicant(s)

Granados et al

Examiner

Medina A. Ibrahim

Group Art Unit

1638



☒ Responsive to communication(s) filed on Oct 2, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1, 3, 5-7, 9-10, 20-22 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☒ Claim(s) 3, 5, 7, 10, and 20-22 is/are allowed.

☒ Claim(s) 1, 6, and 9 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 5-7, 9-10, and 20-22, pending in this application, are under examination.

Claims 20-22 are newly added.

#### ***Withdrawn rejections***

The rejections under 35 USC 112, 2nd paragraph to claim 9 has been withdrawn in view of Applicants' amendment to the claim in the response filed 08 May 2000.

#### ***Claim Rejections - 35 USC § 112***

Claims 1, 6, and 9 remain rejected under 112, first paragraph, as the specification is not enabling for any transformed plant comprising any gene encoding an invertebrate intestinal mucin (IIM) protein, and a method for producing an IIM protein by transforming a host cell with an expression vector comprising a promoter, glutathione- S-transferase gene, and a nucleotide sequence encoding a predetermined protein of any IIM, as stated in the last office action.

Applicants traverse, in pages 2-3, that claim 1 functionally describes the IIM protein, claim 6 describes a method for producing an IIM protein, and that since methods for isolating proteins are well known in the art, a person skilled in the art could easily make and use any IIM protein by following techniques described in the specification and the techniques for protein isolation known in the art. Applicants conclude that no undue experimentation is required to obtain other IIM proteins from other invertebrates. These arguments are not found persuasive.

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As stated in the last office action, claims are broadly drawn to any transformed plant comprising a gene encoding any invertebrate IIM protein, and a method for producing and recovering said protein from any host. The specification provides guidance for the cDNA expression library from *Trichoplusia ni* midgut mRNA and the screening of the library with antiserum specific to the *T. ni* IIM protein. However, the specification fails to provide an evidence that the antibody obtained for the *T. ni* will also be terribly specific to the other IIM proteins covered by the instant claims. No guidance has been presented for the obtention of specific probes, hybridization and wash conditions for the exemplified or non exemplified genes encoding functional IIM proteins or antibodies to the IIM proteins, and it is not clear if any has been isolated from other invertebrates at the time of Applicant's invention. Given the scope of the claims which encompass a transformed plant comprising a gene encoding any invertebrate IIM protein, and a method for producing and recovering said protein from any host, lack of specific guidance for how to obtain genes encoding other IIM proteins, gene hybridization stringency conditions, or gene sequence similarity, and unpredictability in the expression of disease resistance genes or insecticidal proteins in transgenic plants as evidenced by Linthorst et al and Dandekar et al , undue experimentation would have been required by one skilled in the art to practice the invention as broadly claimed.

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Claims 1, 6, and 9 remain rejected under 112, first paragraph, as the specification as the specification does not provide an adequate written description for the invention as broadly claimed, as stated in the last office action.

Applicants traverse, in page 3, last two paragraphs, the specification discloses that antiserum directed to T.ni protein cross-reacted with mid-gut proteins from 18 other insect species (Table 3, pages 31-32 specification) which shows the presence of IIM protein in other invertebrate species. These arguments are not persuasive.

Claims are drawn to a multitude of genes from a multitude of invertebrates, including a multitude of insect and non-insect species, encoding a multitude of functional IIM proteins of undefined physical and structural characteristics, as stated in the last office action. The specification describes only cDNA clones from T.ni encoding IIM protein as set forth in SEQ ID NO: 3 or 4. Given the lack of written description as stated above, a mere cross-reaction of an antiserum to T.ni IIM protein with proteins from 18 other insect species will not envisage a person skilled in the art that the applicant has possession of the genes of the invention as broadly claimed. See, the Synopsis of Application of Written Description Guidelines made available at the USPTO website March 1, 2000. See in particular Examples regarding Genus and Species representatives. See, also, Amgen Inc and University of California disclosed in page 6 of the last office action.

Claims 3, 5, 7, 10, and 20-22 are in condition for allowance.

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1. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The examiner can normally be reached on Monday -Tuesday and Thursday from 7:30AM to 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

mai  
December 7, 2000

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

*David T. Fox*